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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,518	01/28/2002	Toshio Ota	14897-097001/H1-107PCT1-U	5393

26161 7590 11/05/2003

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EXAMINER	
SNEDDEN, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,518	OTA ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *9-10, 13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-8 and 11-12, drawn to DNA, vectors, host cells and method of making protein, classified in class 435, subclass 69.1.

   II. Claims 9-10, drawn to a protein, classified in class 530, subclass 350.

   III. Claims 13-14, drawn to an antibody, classified in class 530, subclass 387.1.

   IV. Claim 15, drawn to a nucleic acid molecule that hybridizes to SEQ ID NO: 1, classified in class 536, subclass 23.1.

   V. Claims 16-17, drawn to a method of screening a compound that binds to the polypeptide, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of invention I are related to the protein of invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the claims of invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay. Thus, they can be unconnected in use and operation.

The nucleic acid of invention I and the antibody of invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody.

However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The nucleic acid molecules of inventions I and IV are related by virtue of their ability to hybridze to each other. However, the nucleic acid molecules would differ in structure and biological function. Additionally, the products are capable of use in materially different methods. For example, the DNA of invention I may be used to produce the protein of invention II; this would not necessarily apply to the product of invention IV.

The product of invention I is not used in the method of invention V. Therefore, invention I is patentably distinct from invention V.

The protein of invention II are related to the antibody of invention III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The product of inventions II and III are unrelated to the product of invention IV. The product of invention IV differs in structure and function from the products of inventions II and III are a thus patentably distinct.

Inventions II and III are related to invention V as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of inventions II and III can be used in a materially different process such as generating antibodies (invention II) or in a method of detecting protein (invention III), for example.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-V, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Andrew Torrance on October 9, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8 and 11-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-10 and 13-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 and 11-12 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The above claims are directed to nucleic acid encoding the protein of SEQ ID NO: 2. The nucleic acid above is disclosed as having utility in making the protein of

SEQ ID NO: 2. The use of the nucleic acid in the method of making a polypeptide that itself has no specific and substantial asserted or well established utility is itself not specific and substantial or well establish. The specification describes the protein as comprising WW domains that are known to be involved in protein-protein interactions. Because of the presence of these domains, the specification teaches that the protein of SEQ ID NO: 2 may regulate signal transduction pathways or gene expression (see page 5). The asserted utility is that protein is associated with the maintenance of smooth muscle differentiation. The specification fails to disclose or provide any convincing evidence that points to an activity for the protein having a function in smooth muscle cell differentiation ans no such relationship is found in the prior art.

Basic research, such as studying the properties of the claimed product itself or the mechanisms in which the material is involved, such as gene expression, do not constitute specific or substantial utilities (see page 27 of the specification). The therapeutic methods disclosed in the specification teach the treatment of unspecified disease or condition (see page 30). Neither the specification nor the art of record disclose any diseases or conditions caused or exacerbated by the protein of SEQ ID NO: 2. The asserted utility in this case essentially is a method of treating an unspecified, undisclosed disease or condition, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use.

Thus, the claimed polynucleotide encoding protein is not supported by either a specific and substantial asserted utility or a well established utility as to the above because the specification fails to assert any well established utility for the protein and neither the

specification as filed nor any art of record disclose or suggest any activity for the protein such that any utility would be well established for the protein.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is also referred to the Guidelines on Written Description published at FR 66(4) 1099-1111 (January 5, 2001) (also available at www.uspto.gov).

The claims recite isolated nucleic acid molecules which hybridize to the nucleic acid of SEQ ID NO: 1, which encode a protein that share the function of protein of SEQ ID NO: 2, or variants of SEQ ID NO: 1 where amino acids are deleted, replaced and inserted. Also, as in claim 2, the claims recite fragments of SEQ ID NO: 2 without any indication as to what function the fragments are to possess. The specification discloses a single isolated cDNA sequence, SEQ ID NO: 1, which encodes a polypeptide sequence, SEQ ID NO. 2. A function of the protein of SEQ ID NO: 2 is not disclosed in the specification. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others

excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Additionally, the claims, as written, however, encompass polynucleotides which vary substantially in length and also in nucleotide composition. The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. Which amino acids can be replaced, deleted or inserted to produce a functional protein? There is no description of the conserved regions which are critical to the structure and function of the genus claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill

in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

7. Claims 1-8 and 11-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "stringent" in claim 1 is a relative term which renders the claim indefinite. The term "stringent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Given broad range of possible hybridization conditions, millions of nucleic acids of unpredicted, non-obvious sequence or structure, could hybridize to SEQ ID NO: 1. Therefore, as the claims describe a large number of structurally unrelated sequences, the claims fail to distinctly claim the subject matter of the invention. Claims 3 and 5 or indefinite as they depend from claim 1 and do not clear up the ambiguity.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gmerek *et al.* (Genbank Accession U13395). Gmerek *et al.* teach the HHCMA56 cDNA that is 98.6% identical to SEQ ID NO: 1 from positions 578-2052. The sequence taught by Gmerek would hybridize to SEQ ID NO: 1 and encode fragments of SEQ ID NO: 2. Thus, the reference anticipates the claimed invention.

11. Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by applicants own admission at page 3. Applicant states "the results of homology search showed that the query clone was identical to the helix clone "C-T2RP3001495". In addition, it was also revealed that the query clone is identical to the gene for Hs.519 Human oxidoreductase (HHCMAS6) of Unigene." Thus, the invention is anticipated by helix clone "C-T2RP3001495" and the gene for Hs.519 Human oxidoreductase (HHCMAS6).

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
November 3, 2003
SKS

Karen Cochrane Carlson, Ph.D

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER